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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,778	10/14/2003	Sau-Hung Spence Leung	5746/B-03-BHJ	3357

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Warner-Lambert Company
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EXAMINER

HOWARD, SHARON LEE

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/684,778	Applicant(s) LEUNG ET AL.	
	Examiner Sharon L. Howard	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-41 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-41 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

Applicant's arguments filed on 12/15/04, with respect to the rejection of claims 31,34-41,48-55 over Blume et al. (USP 6,372,252 B1) in view of Hijiya (USPN 4,562,020), and the rejection of claims 31,34-41,48-55 over Blume ('252) in view of Akiyama et al. (USPN 5,576,025) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new grounds of rejection over claims 31-34-41 is made over Hijiya (USPN 4,562,020) in view of Akiyama (USPN 5,576,025) and a new grounds of rejection of claims 48-55 is made over Oshlack et al. (USPN 5,580,578).

Status of the Claims

Claims 1-30 were previously cancelled without prejudice.

Claims 42-47 were previously cancelled without prejudice.

Claims 31,34-41,48-55 are currently pending in this application.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31,34-41,51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijiya (USP 4,562,020) in view of Akiyama et al. (USP 5,576,025).

Hijiya teaches an edible, water-soluble film comprising pullulan (see col.3, lines 60-65).

Hijiya does not particularly teach a pharmaceutical agent.

However, Akiyama teaches a gastrointestinal mucosa-adherent, solid pharmaceutical preparation adapted to stay long in the gastrointestinal tract for sustained drug release, and a coating composition (see col.1, lines 13-17). Akiyama teaches that the composition comprises water soluble active ingredients such as central nervous system drugs such as antipyretic-analgesic-antiinflammatory agents, peripheral nervous system drugs, autonomic drugs, and the like; antitussives, intestinal function-controlling agents, antacids, antihistaminics, ibuprofen, acetaminophen, phenylephrine hydrochloride, chlorpheniramine maleate, phenylpropanolamine hydrochloride and the reference generically discloses antiulcer drugs (see col.5, lines 53-67, col.6, lines 1-28). Akiyama also teaches that the composition comprises pullulan (see col.4, lines 1-4) and that the solid composition may be provided in a compressed tablet formulation (see col.13, lines 39-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Hijiya in the manner taught by Akiyama. One having ordinary skill in the art would have been motivated to modify the

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composition of Hijiya to include a pharmaceutical agent, with the expectation of achieving a composition which is adapted to adhere to the gastrointestinal mucosa for a prolonged period of time, thereby promoting absorption and increasing the bioavailability of the active ingredient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijiya (USPN 4,562,020) in view of Oshlack et al. (USPN 5,580,578).

Hijiya teaches an edible film comprising pullulan (col.3, lines 60-65).

Hijiya does not particularly teach dextromethorphan.

However, Oshlack teaches a solid controlled release oral formulation (col.4, lines 36-37) containing an active therapeutic agent in amount sufficient to provide a desired therapeutic effect when the formulation is orally administered. Oshlack teaches that the formulation comprises dextromethorphan hydrochloride (see col.17, lines 23-24), including water soluble and water insoluble drugs such as antihistamines, analgesics, non-steroidal anti-inflammatory agents, anti-tussive agents and expectorants (col.16, lines 41-67, col.17, lines 1-62). Oshlack teaches that the formulations are known to be applied to tablets (col.19, lines 50-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Hijiya in the manner taught by Oshlack. One having ordinary skill in the art would have been motivated to modify the composition of Hijiya to include dextromethorphan, with the expectation of obtaining a composition of which is adapted to adhere to the gastrointestinal mucosa for a prolonged period of time, thereby promoting absorption and increasing the bioavailability of the active ingredient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
April 8, 2005



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